3 flot) was achieved in 95% of the 2S group and 92% of the 1S group (p=0.66). Stent thrombosis occurred in 5 patients (25%) of the 2S group at a median of 4.3 days, compared to none (0%) of the 1S group (p< 0.001).
Conclusions: T-stenting of bifurcation lesions does not improve angiographic success and is associated with a substantial risk of stent thrombosis.

1081-50 Predictors of Target Vessel Revascularization After Stenting Coronary Bifurcation Lesions: Insights From a Large Prospective Single-Center Database

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Background: The use of stents is now the gold standard in the majority of coronary lesions. However, use of bare stents in bifurcation lesions remains controversial.
Methods : We assessed the 7 months outcome and predictors of TVR from a large single centre prospective database of patients with bifurcation lesions treated by stent. Follow-up coronary angiogram was performed only in case of clinical or stress test ischemia.
Results: Between 1996-2002, 1149 patients underwent PCI and stent for bifurcation lesion, age 65±9 years, 83% male, 37% unstable angina and 10% acute MI. The left anterior descending bifurcation was involved in 53% of cases and distal left main in 8%. Type B treatment (provisional T stenting of the side branch) was used in 74% of cases, Type A (Systematic T stenting, the side branch first) in 18%, Type D (V stenting) in 6% and Type C (Culotte) in 2%. The main branch (proximal reference diameter 3.1±0.5 mm) was stented in 98.6 % of cases and the side branch (2.4±1.1 mm) in 37.2%. Angiographic success (residual stenosis ≤ 30%) was obtained in 96.3% of cases for the main branch and 92.9 % for the side branch. The ischemic driven TVR rate at 7 months follow-up was 13.2%. Predictors of TVR by univariate analysis were acute coronary syndrome (12.3 vs 8.6%; OR 4.6, p = 0.001), period 1996-98 vs 1999-2002 (16.2 vs 11.8%; OR 0.67, p = 0.01), reference main branch diameter ≤ 2.7 mm (18.8 vs 12.7%; OR 1.53, p = 0.065), non use of type B treatment (24.2 vs 11.0%; OR 0.48, p = 0.001), use of 2 stents (19.1 vs 10.0%; OR 1.92, p = 0.001) and type 4 lesions compared to type 3 lesions (8.3 vs 22.1%; OR 4.6, p = 0.001). By multivariate analysis, independant predictors of 7-months TVR were acute coronary syndromes (OR 6.74, p = 0.001, 95 % CI : 4.66 – 9.88), reference diameter ≤ 2.7 mm (odds ratio 2.03, p = 0.006, 95 % CI : 1.22 – 2.38) and non-use of type B treatment (odds ratio 0.46, p = 0.001, 95 % CI :0.31 – 0.67).
Conclusion: Stenting of bifurcation lesions is associated with a high rate of angiographic success and an acceptable rate of ischemic driven TVR at 7 months. Independent predictors of TVR are acute coronary syndrome, small reference diameter and strategies other than provisional T stenting

1081-51 AST SLK-View™: A Novel Approach for Treatment of Bifurcation Lesions

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Background. Treatment of bifurcation lesions is one of the main challenges of interventional cardiology. Wile maintaining sufficient vessel support and side branch access, SLK-View™ Stent offers a promising approach for the treatment of coronary bifurcation lesions. The aim of this prospective, multicenter trial was to evaluate the safety and feasibility of the SLK-View™ Stent for treatment of a *de novo* lesion that involves a major parent coronary artery and side branch. Methods and Results. A total of 31 pts (67.7 % - male; mean age 61.3±10 years) were treated. Follow-up included clinical assessment at 30 days and angiographic study at 6 months. The location of bifurcations was most frequent in left descending artery/diagonal branch (84%), and was followed by right coronary artery/posterior descending artery (10%) and circumflex/obtuse marginal branch (6%). Stent was successfully delivered to bifurcations in all but 2 pts (93.5%). Procedural success defined as <50% residual stenosis of the parent vessel in the absence of major adverse cardiac events (MACE) was achieved in all pts with successful stent deployment. Six-month MACE were observed in 14(45.1%) pts and were represented by target lesion revascularization in the majority of pts (41.9%). Other results are presented in the Table. Conclusions. SLK-View™ Stent is a safe and effective new solution for treatment of bifurcation lesions. Anti-restenosis drug elution should be considered in this high risk population with this successful platform.

Quantitative Angiographic Data at Baseline and 6-Month Follow-up

Characteristic	Parent vessel			Branch vessel		
	Pre-PCI	Post-PCI	At 6 months	Pre-PCI	Post-PCI	At 6 months
Reference vessel diameter, mm	2.9±0.4	-	-	2.2±0.4	-	-
Minimal lumen diameter, mm	1.1±0.4	2.3±0.5	1.51±0.76	1.4±0.4	1.7±0.4	1.2±0.6
Percent stenosis, %	63.1±12.8	23.5±8.0	49.0±22	37.7±16.7	24.2±13.5	41±26
Vessel with percent stenosis<50%, n (%)	-	29 (100%)	12 (48%)	-	-	8 (32%)

1081-52 Prediction of Death or Myocardial Infarction by Exercise SPECT Scintigraphy Among Patients Who Have Had Recent Coronary Stenting

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Background: Although practice guidelines do not recommend routine exercise- testing of patients after coronary stenting, several small studies have suggested that stress myocardial perfusion imaging can provide prognostic information about future adverse cardiac events.
Methods: We analyzed 420 patients who underwent dual isotope exercise nuclear scintigraphy after coronary stenting between April 1996 and May 2002.Mild ischemia was defined as reversible perfusion defects involving 6-18% of myocardial mass, while severe ischemia involved more than 18% of myocardial mass. The primary endpoint was all-cause mortality or myocardial infarction during a median of 12 months (range 1 to 60) of follow-up.
Results: There were 101 patients (24%) who had mild or severe ischemia. Major events (death or MI) occurred in 70 patients including 24 deaths. Among patients with no ischemia the 1-year event rate was 6.2%, whereas among patients with mild or severe ischemia, the event rates were 11.4% and 9.8% (P=0.006). After adjusting for age, gender, standard cardiac risk factors, cardiac history, left ventricular ejection fraction, angiographic findings, procedural variables, exercise capacity and heart rate dynamics, the presence of scintigraphic evidence of ischemia predicted death or MI (adjusted hazard ratio for 1 SD increase in mass of ischemic myocardium 1.37, 95% CI=1.11-1.68, p=0.003). The presence of ischemia similarly predicted events in asymptomatic patients.
Conclusions: Among patients who have undergone recent coronary stent placement, nuclear perfusion defects independently predicted risk of death or myocardial infarction.

1081-53 Debulking of Chronic Total Occlusions With Rotational or Directional Atherectomy Before Stenting Trial: A Multicenter Randomized Study

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Background: Previous randomized studies have shown that stenting reduces restenosis and reocclusion rates of successfully recanalized chronic coronary total occlusions (CTO) compared with balloon angioplasty (BA) alone, however the restenosis rate after stenting still remains high. Calcified plaque or massive plaque burden in CTO is considered to interfere with full stent expansion and be a cause of restenosis. **Methods:** DOCTORS (Debulking Of CTO with Rotational or directional atherectomy before Stenting) is a multicenter randomized trial aimed to examine the efficacy of pre-stent plaque debulking by rotational or directional atherectomy (RA/DCA) on reduction of restenosis. After successful recanalization of CTO (TIMI flow =< 1, estimated occlusive duration >= 1 month) by using a conventional wire, the physician determined the indication of RA or DCA. Then, patients were randomly assigned to the debulking (D) group or the non-debulking (ND) group according to the debulking device the physician decided. In the D group, RA or DCA was performed and stents were implanted to fully cover the lesion. In the ND group, stents were implanted after conventional BA. Serial quantitative angiography (QCA) and intravascular ultrasound (IVUS) examination were performed at the procedure and 6 month follow-up (Fu). The primary endpoint was the angiographic restenosis rate. Secondary endpoints were clinical outcomes by 1 year and QCA and IVUS parameters.
Results: In Japanese 21 centers, 271 patients were enrolled (~ July 2003). Of those, 138 patients were assigned to the D (RA: 90, DCA: 48) and 133 to the ND group. Baseline characteristics did not differ. There were 4 unsuccessful cases; 3 in the D and 1 in the ND group (NS). Major adverse cardiac event rate by 30 days was also similar (1.6% versus 0%). Total implanted stent length was significantly longer in the ND group (25.7±10.8 versus 28.8±12.0 mm; p=0.03). Fu angiographic data has been collected in 197 patients to date. Target vessel revascularization rate was higher in the ND group (26.8 versus 41.2%; p=0.04). **Conclusion:** Pre-stent debulking for CTO is safe and may be effective in prevention of restenosis. Final Fu angiographic results and QCA data will be presented.

1081-54 Effect of Diabetes on Five-Year Outcomes After Coronary Stent Implantation

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Background: Diabetes (DM) is associated with significantly increased clinical restenosis in the first year after coronary stenting. The DM effect on target lesion stability after one year and long-term overall cardiac clinical outcome after second-generation coronary stents has not been reported. **Methods:** We reviewed clinical outcomes for a subset of patients consented for long-term follow-up as part of pivotal stent trials evaluated for FDA approval. We report pooled data for 1228 such patients with mean 4.4 years follow-up. A Cox proportional hazards model was used to evaluate the independent effect of diabetes on overall mortality and the 5-year composite cardiac event rate. **Results:** DM patients were older (64 ± 10 vs. 62 ± 11 years, p=0.008), more frequently women (41% vs. 29%, p=0.001) and had more frequent 3 vessel disease (11.4% vs. 7.1%, p=0.02). At one year, target lesion revascularization (TLR) was significantly more common for DM (Table). During years 2-5, TLR was infrequent in either group, but the incidence of ischemic events and death was increased among DM patients. DM was a significant independent predictor of the 5-year composite outcome (Hazard Ratio 1.5, p=0.0001). **Conclusions:** 1) Diabetes was not associated with increased TLR after one year. 2) Despite similar stability of

the target lesion during long-term follow-up, DM was associated with significantly increased other major cardiac ischemic events and a non-statistically significant increase in mortality.

Endpoint	Diabetes N=263	No Diabetes N=965	P
One-Year Outcomes			
Composite	33.1%	24.6%	<0.01
Death	1.1%	0.8%	>0.20
MI	9.5%	7.6%	>0.20
TLR	16.9%	11.0%	0.02
Other Revascularization	27.2%	19.0%	<0.01
Five-Year Outcomes			
Composite	58.5%	42.8%	<0.01
Death	10.4%	7.7%	0.14
MI	12.2%	9.7%	>0.20
Death or MI	20.9%	16.9%	0.08
New unstable angina	7.6%	4.3%	0.03
New onset CHF	3.4%	1.0%	<0.01
TLR	23.2%	16.7%	0.02
Other Revascularization	34.0%	24.9%	<0.01

1081-55 **Influence of Gender on In-Hospital and Long-Term Clinical Outcomes Following Percutaneous or Surgical Revascularization: A Report From the Arterial Revascularization Therapies Study (ARTS)**

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Background: Previous studies have shown that women (W) undergoing coronary revascularization (CR) have a higher incidence of in-hospital complications than men (M). To determine whether W have an unfavorable long-term outcome after percutaneous (PCI) or surgical (CABG) CR compared with M, we evaluated patients (pts) enrolled within the Arterial Revascularization Therapies Study (ARTS).
Methods: We prospectively evaluated 1205 pts with angina or silent ischemia and multivessel (MV) disease randomized to PCI or CABG of whom 283 (23%) were W. The clinical presentation, in-hospital complications and the freedom from major adverse cardiac and cerebrovascular events at 3-years were evaluated.
Results: W were older (65 vs 59 years), with a higher prevalence of hypertension (59% vs 40%, p(less)0.001), hypercholestelolemia (71% vs 54%, p(less)0.001), family history for coronary artery disease (52% vs 37%, p(less)0.001) and stable angina (64% vs 57%, p=0.03) than M, but had a lower incidence of history of myocardial infarction (35% vs 46%, p(less)0.001) or current smoking (18% vs 30%, p(less)0.001). The presence of unstable angina, the extent of coronary artery disease and the location of the stenosis was similar in W and M. W assigned to CABG received the same number of arterial conduits and had similar number of distal anastomoses compared to M (2.5$\pm$0.7 vs 2.5$\pm$0.7 and 2.6$\pm$1.0 vs 2.8$\pm$1.1 respectively, p:ns). A higher incidence of in-hospital death (3.2% vs 0.5%, p=0.001) and major bleeding complications (4.2% vs 1.5%, p=0.01) were observed in W compared to M, because of increased mortality in W post-CABG (CABG=4.1%, PCI=2.17%) and bleeding events following PCI (PCI=7.2%, CABG=1.38%). At an average of 3 years follow-up the survival without death / cerebrovascular accident / myocardial infarction / revascularization was similar in M and W. (M : PCI=66.2%, CABG=83.9% ; W : PCI = 64.5%, CABG=81.4%).
Conclusion: The 3 year outcomes of W with MV disease undergoing CR are similar to those in M. Despite the similarity in long-term outcomes, there are several gender-specific differences in clinical characteristics and risk factors profile resulting in higher in-hospital complications in W.

1081-56 **Evolution of Percutaneous Coronary Intervention in Acute Myocardial Infarction: Insights From a Large Single Center Database**

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Background: Over the last several years, the number of PCI in acute myocardial infarction (AMI) has increased and stent has become an established gold standard with increased use of Gp2b3a inhibitors as an adjunctive therapy and facilitated PCI is being currently evaluated. The objectives of this study is to assess the evolution and trends of PCI in AMI over the last eight years from a single center prospective registry.
Methods: Our registry started in January 1995 with pre defined strategy in AMI $\leq$ 12 hours: no contra-indication regarding pre-hospital thrombolysis, direct admission in the cathlab for immediate coronary angiogram, angioplasty when indicated and stent when feasible.
Results: From 1995 to 2002, a total of 1824 consecutive patients underwent PCI in AMI. They were 61.8$\pm$14.4 years, 78% males, 17% diabetes mellitus, 12% previous MI, 45% anterior MI and 13% in cardiogenic shock. Evolution is summarized below.

	1995-96	1997-98	1999-2000	2001- 02
Prehospital thrombolysis (%)	13	18	18	31
GP IIbIIIa (%)	0	5	10	11
Stent (%) Direct Stenting (%)	84 10	90 14	92 47	95 67
Radial approach (%)	2	10	39	55
Angiographic success (%)	99	99	100	100
Final TIMI 3 (%)	89	89	92	95
Repeat PTCA (%)	7.0	2.9	2	2.4
In hospital Death (%)	13	10	8	8

Conclusion: From 1995 to 2002, progress in PCI in AMI is remarkable with significant increases in pre-hospital thrombolysis, radial approach, glycoprotein IIb/IIIa inhibitors, stents and direct stenting. Outcome improved markedly with higher final TIMI 3 flow and reduced death and re-intervention.

1081-57 **Randomized Comparison Between Stent and Balloon in Diabetic With ST-Segment Elevation Myocardial Infarction Undergoing Primary Angioplasty: A Substudy of the Zwolle-6 Randomized Trial**

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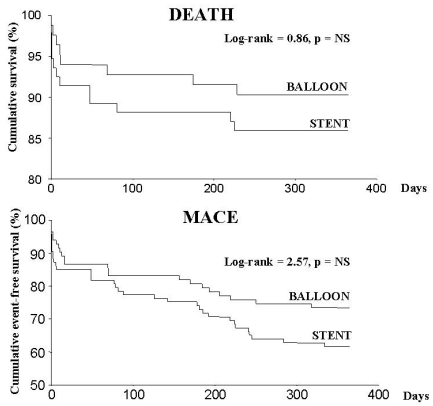
Background. Currently available randomized trials on primary stenting for ST-segment elevation myocardial infarction (STEMI), have enrolled highly selected patients, after the initial angiogram. In the Zwolle 6 randomized trial, 1683 patients with STEMI were randomized, before angiography, to stent (S) or balloon (B), without any exclusion criteria. In this study we present data from the subanalysis conducted in diabetic patients.
Methods. Among a total of 1683 consecutive patients with STEMI enrolled in the study, 177 (10.5%) suffered from diabetes (S = 94 and B = 83). The primary endpoint was MACE (death, reinfarction, and/or reintervention at 1-year).
Results. The cross-over rates from B to S and S to B were 30.3% and 20.2%, respectively. No difference was observed in 1-year mortality and MACE according to intention-to-treat analysis (see figure).
Conclusions. Our study is the first randomized trial comparing stenting and balloon angioplasty in a large cohort of unselected, consecutive patients. This subanalysis showed that routine stenting does not improve clinical outcome in diabetic patients undergoing primary angioplasty for STEMI.



1081-58 **Long-Term (Seven-Year) Outcomes After Bare Metal Coronary Stenting for Unprotected Left Main Coronary Stenosis**

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Background) Drug eluting stent may spread the indication of coronary intervention. Therefore, the longer-term efficacy of bare metal coronary stenting for unprotected left main coronary artery (LMCA) stenosis is necessary to be evaluated.
Methods) Between March 1991 and August 1996, 36 consecutive patients (pts) with unprotected LMCA stenosis underwent elective stenting. Treated pts were divided into 2 groups; good candidate group (GC:17pts) for coronary artery bypass grafting(CABG), and poor candidate group (PC 19pts) with risk factors; old age (>75 yrs) in 8pts, cerebrovascular disease in 7 pts, prior CABG in 5 pts, poor LV (ejection fraction<40%) in 2 pts, COPD in 1 patient (pt), cancer in 1 pt, and poor run off in 1 pt. Clinical follow-up was performed with mean interval of 64±36 months.
Results) The procedure success rate was 100%. 3-6month angiographic follow-up was performed in 34 pts, and the restenosis rate was 21% (7/34). During the follow-up period, thirteen pts were died (3 cardiac, 10 noncardiac). Estimated event free rate from cardiac